

CLAIMS:

1. A balloon catheter for performing an angioplasty procedure on a lesion in a vessel [,]comprising a flexible elongate catheter shaft having proximal and distal extremities, a balloon secured to the distal extremity of the catheter shaft and having proximal and distal extremities and having an interior and movable between deflated and inflated conditions, the catheter shaft having a balloon inflation lumen extending from the proximal extremity to the distal extremity of the catheter shaft and opening into the interior of the balloon, a fitting for supplying an inflation medium to the inflation lumen for causing movement of the balloon from the deflated condition to the inflated condition, said balloon having an outer surface extending from the proximal extremity to the distal extremity of the balloon which moves outwardly radially upon inflation of the balloon and at least one flexible elongate element extending over the outer surface of the balloon from the proximal extremity to the distal extremity of the balloon, said flexible elongate element being secured about the catheter shaft in positions spaced longitudinally away from the outer surface of the balloon to permit expansion of the balloon and to cause movement of the flexible elongate element into engagement with the lesion to form a longitudinal channel in the lesion.

2. A balloon catheter as in Claim 1 wherein a plurality of flexible elongate elements are provided which are spaced apart circumferentially of the balloon

3. A balloon catheter as in Claim 1 wherein the flexible elongate element is secured to the proximal extremity of the balloon to permit sliding movement of the

flexible elongate element relative to the catheter shaft during inflation of the balloon.

4. A balloon catheter as in Claim 3 wherein the  
5 distal extremity of the flexible elongate element is secured  
in a fixed longitudinal position with respect to the  
balloon.

5. A balloon catheter as in Claim 1 wherein at least  
10 one of the proximal and distal extremities of the flexible  
elongate element is formed of an elastic material to permit  
stretching of the flexible elongate element during inflation  
of the balloon and retraction during deflation of the  
balloon.

15 6. A balloon catheter as in Claim 4 wherein both of  
the proximal and distal extremities of the flexible elongate  
element are formed of an elastic material

20 7. A balloon catheter as in Claim 1 wherein said  
balloon when in a deflated condition is folded over the  
flexible elongate element to prevent injury to the vessel  
during delivery of the balloon to the lesion in the vessel.

25 8. A balloon catheter as in Claim 1 wherein said  
flexible elongate element is substantially circular in cross  
section.

30 9. A balloon catheter as in Claim 1 wherein said  
flexible elongate element is substantially triangular in  
cross section.

10. A balloon catheter as in Claim 9 wherein said  
outer surface of the balloon in the inflated condition in

cross section has a curved surface and wherein said flexible elongate element which is triangular in cross section has a surface in cross section which is concave to accommodate the curved outer surface of the inflated balloon and to provide  
5 a better fit between the balloon and the flexible elongate element as the balloon is expanded to bring the flexible elongate element into engagement with the lesion in the vessel.

10        11. A balloon catheter as in Claim 9 wherein said flexible elongate element has a longitudinal axis and has longitudinally spaced apart cutouts therein to increase the flexibility of the flexible elongate elements along the longitudinal axes.

15        12. A balloon catheter as in Claim 1 wherein filler material is disposed in the cutouts.

20        13. A balloon catheter as in Claim 12 wherein said filler is a relatively soft material selected from an adhesive [and] or a polymer.

25        14. A balloon catheter as in Claim 1 wherein said flexible elongate element is formed of a rigid flexible [relatively hard] material selected from stainless steel, Nitinol, Nylon, fluoropolymer and carbon fiber.

30        15. A balloon catheter as in Claim 2 wherein said flexible elongate elements are formed as a part of a cage mounted over the balloon and comprising first and second spaced apart rings secured to the flexible elongate elements, said rings being spaced apart a sufficient distance so that the outer surface of the balloon can engage the flexible elongate elements, said rings being sized so

that the case is slidably mounted on the catheter shaft and permitting the case to be slipped onto and over the balloon when the balloon is in a deflated condition and serving to retain the flexible elongate members in engagement with the  
5 balloon during inflation of the balloon.

16. A method for manufacturing a balloon catheter for performing an angioplasty procedure on a lesion in a vessel, fabricating a balloon catheter with a flexible elongate catheter shaft with proximal and distal extremities and having a balloon disposed on the distal extremity, providing at least one flexible elongate element extending longitudinally of the balloon and having proximal and distal extremities and securing the proximal and distal extremities 10 of the flexible elongate element about the catheter shaft so that they are disposed away from opposite ends of the  
15 balloon.

17. A method as in Claim 16 further including 20 providing a plurality of flexible elongate elements spaced apart circumferentially of the balloon.

18. A method as in Claim 17 wherein the proximal and distal extremities are secured to the catheter shaft.  
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19. A method as in Claim 18 wherein the proximal and distal extremities are secured to rings sized so that they can slip over a deflated balloon mounted on the distal extremity of the shaft but cannot slide off of the balloon  
30 when the balloon is inflated.